DEC 1 9 2001

Hollister Incorporated
Microgyn Plus (w/10Hz) Stimulation Device

Safety and Effectiveness Summary

1. Submitter's name, Address and Contact Person

Submitter	Contact Person
Hollister Incorporated	Joseph S. Tokarz
2000 Hollister Drive	Manager, Regulatory Affairs
Libertyville, IL 60048	Ph : (847)680-2849
	Fax: (847)918-3860

Date Summary Prepared – December 18, 2001

2. Name of Device:

Hollister Microgyn Plus Stimulation Device

3. Name of Predicate Device(s)

InCare Microgyn Plus Device, K963222
Elpha 2000 Conti Device, K964738

4. Description of Device

The proposed Microgyn Plus Stimulation Device is intended to provide electrical stimulation for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of urinary incontinence in women.

The proposed Microgyn Plus is a battery-powered device that delivers a regulated stimulus to the nerves and muscles of the pelvic floor. The stimulus is administered by attaching an anatomically shaped probe to the device and then inserting the probe into the patient's vagina or anus. When stimulation is delivered the body responds by contracting the muscles of the pelvic floor.

5. Statement of Intended Use

The proposed Microgyn Plus Stimulation Device is intended to provide electrical stimulation for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of urinary incontinence in women.

6. Statement of Technological Characteristics of the Device

The proposed Microgyn Plus is a battery-powered device that delivers a regulated stimulus to the nerves and muscles of the pelvic floor. The stimulus is administered by attaching an anatomically shaped probe to the device and then inserting the probe into the patient's vagina or anus. The Microgyn Plus provides balanced biphasic stimulation

pulse. The pulse has a positive and negative phase such that the net charge applied to the patient is zero.

The proposed Microgyn Plus is a current controlled device that provides an output that is adjustable from 0-60 milliamperes. The device also has the ability to select between three frequencies (10, 50, 100 Hz) depending on the frequency selected by the caregiver and the individual needs of the patient.

The proposed Microgyn Plus is identical to the predicate device (K963222) in electrical characteristics except that 10 Hz has been substituted for 20Hz.

7. Conclusion

Based upon the information presented within this pre-market notification it is concluded that the proposed Microgyn Plus Stimulation Device is safe and effective for its intended use and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 2001

Mr. Joseph S. Tokarz
Manager, Regulatory Affairs
Hollister Incorporated
2000 Hollister Drive
LIBERTYVILLE IL 60048-3781

Re: K013141
Trade/Device Name: Microgyn Plus
Stimulation Device (10 Hz)
Regulation Number: 21 CFR §876.5320
Regulation Name: Nonimplanted electrical
continence device
Regulatory Class: Class II
Product Code: 78 KPI
Dated: September 19, 2001
Received: September 20, 2001

Mr. Joseph S. Tokarz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Hollister Incorporated
Microgyn Plus (w/10Hz) Stimulation Device

Statement of Intended Use

510(k) Number (if Known): K013141

Device Name: Microgyn Plus Stimulation Device

Indications For Use:

The Microgyn Plus Stimulation Device is intended to provide electrical stimulation for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of urinary incontinence in women.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter-Use ____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David G. Hoffman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013141